

JUN 14 2000

Subject: Summary - 510(k) 000893

Product: Starion Instruments Surgical Power Supply

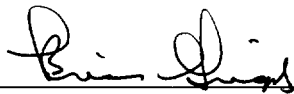
Summary:

This summary of 510(k) safety and effectiveness data is being submitted in accordance with the requirements of 21 CFR 807.92.

The Starion Instruments Surgical Power Supply is a reusable, AC powered unit intended for use only with Starion Cautery Instruments for the simultaneous cutting and cauterization of soft tissue during surgery. The Food and Drug Administration has classified thermal cautery units as Class II devices (21 CFR 886.4115).

The Starion Instruments Surgical Power Supply is substantially equivalent in terms of intended use, target population, energy output, and principles of operation to the Starion Instruments Battery Pack Power Supply, a legally marketed predicate device which has been granted marketing clearance via K990728.

The Starion Instruments Surgical Power Supply features an on/off switch, green power-on LED indicators, two outlets for connection to Starion Cautery Instruments, and an audible tone to indicate activation of the instrument heating element.



Brian Grigsby - Submitter/Contact Person
Vice President, Quality and Regulatory Affairs
Starion Instruments Corporation
20665 Fourth Street
Saratoga, CA 95070
Phone (408) 741-8773
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3/17/00
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2000

Mr. Brian Grigsby
Vice President, Quality and Regulatory Affairs
Starion Instruments
20665 Fourth Street
Saratoga, California 95070

Re: K000893
Trade Name: AC Powered Thermal Cautery Unit
Regulatory Class: II
Product Code: HQO
Dated: March 17, 2000
Received: March 20, 2000

Dear Mr. Grigsby:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.


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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): 000893

DEVICE NAME: AC Powered Thermal Cautery Unit

INDICATIONS FOR USE:

For use only with Starion Cautery Instruments for the simultaneous cutting and cauterization of soft tissue during surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Kochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000893

Prescription Use f
(Per 21 CFR 901.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)